REMARKS

This Amendment is submitted in response to the non-final Office Action mailed on October 20, 2006. A petition for a two month extension of time is submitted herewith. The Director is authorized to charge $450.00 for the petition for extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112843-44 on the account statement.

Claims 1 and 3-25 are pending in this application. Claim 2 was previously canceled. In the Office Action, Claim 17 is rejected under 35 U.S.C. §112, first paragraph, Claims 15-17 are rejected under 35 U.S.C. §112, second paragraph, Claims 1-2 and 5 are rejected under 35 U.S.C. §102 and Claims 1 and 3-25 are rejected under 35 U.S.C. §103. In response Claims 1, 17, 20 and 23 have been amended. These amendments do not add new matter. In view of the amendments and/or for the response set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claim 17 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Patent Office asserts that the specification does not enable one to practice the claimed methods of preventing the recited anandamide mediated ailments. Applicants respectfully disagree. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the specification coupled with information known in the art without undue experimentation. In fact, a patent need not teach, and preferably omits, what is well known in the art. See, MPEP 2164.01.

As set forth in the present specification, U.S. Patent No. 5,874,459 teaches that anandamide may act as a ligand which interacts with cannabinoid receptors in the central nervous system and gut and/or immune cells and tissues. Beside this, numerous physiological effects (e.g. calming effects and effects on the immune system) of anandamide are mentioned in prior art literature as well as in the present application. See, specification, page 4, line 4 to page 5, line 20.

For those skilled in the art, the physiological function of CB1 and CB2 receptors, as well as functional disorders in which these receptors are involved are understood. On the basis of this

general knowledge of a skilled person and in combination with the information provided in the present specification, the knowledge concerning the treatment or prevention of a specific ailment may be readily transferred to other anandamide mediated ailments such as those listed in Claim 17.

Applicants also respectfully submit that one having ordinary skill in the art would be capable of practicing this method without undue experimentation. Claim 17 is essentially directed to, in part, administering a therapeutically effective amount of a composition that is metabolised to a compound having anandamide activity for use as a medicament, wherein the compound comprises an LCPUFA which is a polyunsaturated fatty acid of 16-28 carbon atoms having from 2 to 6 double bonds, and having a moiety such as methyl-, branched-, cyclic-, conjugated-, non-methylene interrupted-, epoxy-, furanoid-, hydroxyl-, allylic-, trans-, or seleno to a patient, for example, at risk of an anandamide mediated ailment. Methods of administering compositions to persons are well known in the art. The specification discloses examples of preparations of nutritional compositions comprising the LCPUFA. Verifying the prevention of the anandamide mediated ailment can readily be determined through routine experimentation.

In addition, the skilled artisan understands that the scope of Claim 17 relates to the prevention of anandamide mediated ailments as taught by the specification. Although the Patent Office presently appears to interpret this as if Claim 17 includes every source of a broadly described ailment, Applicants respectfully submit that the preventing of an anandamide mediated ailment concerns those ailments relevant to anandamide activity in accordance with Claim 17. As a result, the specification along with the knowledge the skilled artisan would enable one to practice the claimed invention without undue experimentation.

Applicants respectfully submit that compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. See, MPEP 2164.02. An example may be "working" or "prophetic." A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. In fact, the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Although studies have not been conducted in the individual cases for every listed

ailment, these studies are within the capabilities of the skilled artisan and do not require undue experimentation. Moreover, it is understood by the skilled artisan that compounds used for treating an ailment can also be used for preventing that ailment. Based on at least these noted reasons, Applicants believe that Claim 17 fully complies with 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that the rejection of Claim 17 under 35 U.S.C. §112, first paragraph, be withdrawn.

In the Office Action, Claims 15-17 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Patent Office asserts that the health problems are not specified and are too broad. In response, Applicants respectfully submit that each of the listed ailments are understood by the skilled artisan. For example, Applicants are not directed to every preventing and treating every source of a broadly described ailment. Instead, the claimed methods of prevention and treatment are directed to anandamide mediated ailments or ailments as they relate to anandamide activity, which are readily known and understood by the skilled artisan. As a result, the skilled artisan would understand the metes and bounds of Claims 15-17 in view of the specification and their own knowledge. Based on at least these noted reasons, Applicants believe that Claims 15-17 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 15-17 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1-2 and 5 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,618,955 to Mechoulam et al. ("*Mechoulam*"). Applicants respectfully disagree with and traverse this rejection for at least the reasons set forth below.

Independent Claim 1 recites, in part, a composition for oral administration comprising a precursor that is metabolised to a compound having anandamide activity for use as a medicament. In addition, Applicants have amended Claim 1 to remove R" being $NHCH_2CH_2OH$. Essentially, Claim 1 is directed to a precursor having the structure recited in Claim 1 that is metabolised and not to the final anandamide composition. The mechanism of action plays a role in metabolising the precursor. In contrast, Applicants respectfully submit that *Mechoulam* fails to disclose or suggest every element of Claim 1.

Mechoulam fails to disclose or suggest the precursor having the structure recited in Claim 1 that is metabolised to a compound having anandamide activity. The Patent Office alleges that

because *Mechoulam* discloses the same formula of anandamide, the mechanism of action should not be given patentable weight. See, Office Action, page 11. Applicants respectfully disagree and submit that the *Mechoulam* does not disclose the same formula of anandamide in accordance with amended Claim 1 and therefore does not disclose the same mechanism of action.

Moreover, *Mechoulam* is directed to polyunsaturated fatty acid amides and their derivatives, which are themselves final synthesis or end products. See, *Mechoulam*, column 1, lines 10-16. As a result, they are not further metabolised to a compound having anandamide activity as required, in part, by Claim 1. In fact, *Mechoulam* fails to disclose or suggest anywhere metabolising a precursor to a compound having anandamide activity. The *Mechoulam* compounds exhibit physiological activity and are useful as active ingredients in pharmaceutical compositions for the treatment of several diseases. Nevertheless, *Mechoulam* is entirely directed to the use of final synthesis or end products, namely, the polyunsaturated fatty acid amides and their derivatives and not any to any compounds utilizing the intermediates or precursors for forming these polyunsaturated fatty acid amides.

As discussed previously, Claim 1 is directed to compositions utilizing a precursor (e.g. intermediate) that is metabolised to form a compound having anandamide activity. For example, the precursor can be metabolised endogenously or within the human body to form a compound having anandamide activity. In contrast, *Mechoulam* discloses compounds that exhibit anandamide activity that are already in their final form prior to entering the body and not further metabolised in the body. Consequently, *Mechoulam* fails to disclose or suggest precursors that are metabolised to a compound having anandamide activity and used as active compounds in a nutritional composition as required, in part, by Claim 1. For the reasons discussed above, Applicants respectfully submit that Claim 1 and Claims 2 and 5 that depend from Claim 1 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicants respectfully request that the rejection of Claims 1-2 and 5 under 35 U.S.C. §102 be withdrawn.

In the Office Action, Claims 1 and 3-25 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Mechoulam* in view of the combination of WO 96/37200 to Stordy et al. ("*Stordy*"), U.S. Patent No. 5,874,459 to Makriyannis et al. ("*Makriyannis*") and WO 94/28913

to Kyle et al. ("*Kyle*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Claim 17 has been amended for clarification purposes. The amendment is supported in the specification, for example, at page 6-7. The present claims are directed to, in part, an agent that is suitable for the treatment of a variety of different diseases without give rise to known side affects such as nausea or cramping. Additionally, the agent may be easily incorporated by an individual. Thus, the present invention provides naturally occurring precursors that are metabolised to a compound exhibiting anandamide activity. Surprisingly, Applicants have found that a composition containing such an agent may be useful for the treatment of a variety of diseases. In contrast, even if combinable, the cited references fail to disclose or suggest every element of the present claims.

As discussed previously, *Mechoulam* is deficient with respect to the present claims. For example, *Mechoulam* fails to disclose or suggest a precursor having the structures recited, in part, by the present claims that is metabolised to a compound having anandamide activity. Instead, the distinguishable compounds specified in *Mechoulam* are final synthesis or end products and thus not identical to the polyunsaturated acid precursors or intermediates of the present claims. *Mechoulam* also fails to disclose or suggest that any such precursor or intermediates used for the synthesis of the respective acid amides should be incorporated in a nutritional composition as required, in part, by the present claims.

Stordy fails to disclose or suggest a precursor having the structures recited, in part, by the present claims that is metabolised to a compound having anandamide activity. Instead, *Stordy* is directed to a method for preparing a composition to be used for treating disorders such as dyslexia, inadequate night vision or dark adaptation. Moreover, *Stordy* is directed to DHA, which is a non-modified polyunsaturated acid. Consequently, *Stordy* fails to disclose or suggest compositions for oral administration comprising a naturally occurring precursor that is metabolised to a compound having anandamide activity, and specifically, the precursors having the moieties as required, in part, by the present claims.

Makriyannis fails to disclose or suggest a precursor having the structures recited, in part, by the present claims that is metabolised to a compound having anandamide activity. Rather, *Makriyannis* is directed to a method for inhibiting anandamide amidase in an individual or

animal and novel inhibitors of anandamide amidase. In fact, *Makriyannis* relates to a completely different objective because the compounds specified therein are compounds capable of inhibiting the degradation of anandamide by inhibiting the enzyme anandamide amidase, which teaches away from the claimed invention. See, *Makriyannis*, column 3, lines 38-60. In contrast, the present claims pertain to precursors that are metabolised to a compound exhibiting anandamide activity. This difference in mode of action explains the different chemical structures of the compounds used in *Makriyannis*. Consequently, there is no evidence that the composition in *Makriyannis* may successfully be used for the specific purpose of the claimed invention.

Finally, *Kyle* fails to disclose or suggest a precursor having the structures recited, in part, by the present claims that is metabolised to a compound having anandamide activity. Instead, *Kyle* merely specifies the use of non-modified polyunsaturated acids like DHA or ARA. *Kyle* also fails to disclose or suggest that the polyunsaturated acids have the moiety as required, in part, by the present claims. For at least the reasons discussed above, the combination of *Mechoulam* in view of *Stordy*, *Makriyannis* and *Kyle* does not teach, suggest, or even disclose the claimed invention, and thus, fails to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 1 and 3-25 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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